



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Population Assessment of Tobacco and Health (PATH) Study (NIDA)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on June 30, 2015, pages 37276 - 37277 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget,

Office of Regulatory Affairs, OIRA_Submission@omb.eop.gov or by fax to (202) 395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project, contact: Dr. Kevin P. Conway, Deputy Director, Division of Epidemiology, Services, and Prevention Research, NIDA, NIH, 6001 Executive Boulevard, Room 5185, Rockville, MD 20852; or call non-toll-free number (301) 443-8755 or E-mail your request, including your address to: PATHprojectofficer@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Cognitive Interviews and Focus Groups for the Population Assessment of Tobacco and Health (PATH) Study (NIDA), 0925-0663, Expiration Date 11/30/2015, Revision, National Institute on Drug Abuse, National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request for the Population Assessment of Tobacco and Health (PATH) Study to conduct cognitive interviews and focus groups, to support the development of the Study's questionnaires and other materials. The PATH Study is a national longitudinal cohort study of tobacco

use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17; the Study conducts annual interviews and collects biospecimens from adults to inform FDA's regulatory actions under the Family Smoking Prevention and Control Act. Cognitive interviews and focus groups are qualitative methods to assess how people interpret, process, retrieve, and respond to phrases, questions, response options, and product images that may be used in the development of the PATH Study's questionnaires and other materials. These methods have previously been used to help the PATH Study improve the comprehensibility of its materials for Study participants, and to increase efficiencies in data collection and reduce duplication and its associated burden on participants and the public.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total annualized burden hours are 2,617.

Estimated Annualized Burden Hours

Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Completing eligibility screener	Youth	1,600	1	10/60	267
	Adults	2,400	1	10/60	400
Examining concepts to be measured in PATH Study	Youth	100	1	90/60	150
	Adults	200	1	90/60	300
Examining assent forms for participation in PATH Study	Youth	200	1	90/60	300
Examining consent forms for participation in PATH Study	Adults	200	1	90/60	300
Examining other	Adults	200	1	90/60	300

Activity Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
forms and materials to support PATH Study data collection					
Examining PATH Study questionnaires	Youth	100	1	90/60	150
	Adults	300	1	90/60	450

Dated: October 7, 2015

Genevieve deAlmeida-Morris

Project Clearance Liaison

NIDA, NIH

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